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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,773	09/14/2000	Simon F. Williams	TEPH 102	1585

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EXAMINER

BHATTI, TAHIRA H

ART UNIT	PAPER NUMBER
1627	#8 ?

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/661,773	WILLIAMS ET AL.
	Examiner	Art Unit
	Tahira H Bhatti	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 and 29-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Office Action

1. Receipt is acknowledged of IDS, and extension of time, dated, 8/24/01, and 2/15/02.

Status of the Claims:

2. Applicant's election with traverse of Group I (claims 1-17 and 27-32) in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the subject matter of Group I is not distinct from either that of Group II or that of Group III. This is not found persuasive because the inventions of groups I and II or III are related as product and process of use, and the product of group I can be used for the treatment of other diseased conditions, and, treatment of osteoarthritic knees in Group III can be treated by other different and/or patentably distinct product. The repairing of tissue in Group II can be treated by any other compound or composition or product using different methods, which would be completely different from the composition of Group I. The requirement is still deemed proper and is therefore made FINAL.
3. Claims 18-28 are rejected in response to restriction requirements dated, 2/15/02.
4. Claims 1-17 and 29-32 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 7, 11, 12, 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The following enumerated reasons apply.

- I. Claim 7 recites the limitation "particles", There is no antecedent basis for this limitation in the claim.
- II. Claim 11 and 12 recite, the molecular weight of "polyhydroxyalkanoate less than 100,000, and in claim 12 the molecular weight of polyhydroxyalkanoate less than 50, 000. The applicant has failed to define the unit, whether the weight is in Daltons or kilo-daltons i.e how is it measured or weighed.
- III. Claim 31 recites "parts" which is not defined, as to what parts the applicant is referring to.
- IV. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

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to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation dyes and compounds, and the claim also recites anti-microbial or anti-inflammatory activity which is the narrower statement of the range/limitation.

7. . Claims 15 is rejected under 35 U.S.C.112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. The present claim 15 is directed to a composition of claim 1 to further comprise agents e.g. dyes, compounds with anti-microbial activity, anesthetics, adjuvants, anti-inflammatory compounds, surfactants, steroids, lipids, enzymes, antibodies, and hormones. in which there is no claimed structure or other identifying characteristics presented with respect to the final specific composition or for that matter the chemical properties and functions thereof.

9. The specification description directed to polyhydroxyalkanoate, clearly does not provide an adequate representation, regarding the composition further comprising an agent selected from the groups in claims 15, made by the presently claimed invention.

10. With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

11. Although directed to DNA compounds, this holding would be deemed to be applicable to any compound; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

12. In the present instance, the composition comprising agents in claim 15 contains no identifying characteristics regarding their function or properties. The specification also does not provide sufficient information regarding these groups.

13. In this regard, applicant is referred to the seminal case of *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and the resulting "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001).

14. It is first noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co*

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15. As pointed out in the above rejection, the specification dose not discloses any examples that are neither representative of the claimed genus of reactions, nor is it clear that they represent a substantial portion of the claimed genus..In the present instance, the *claimed* invention contains no identifying characteristics regarding the agents in claim 15.

Claim Rejections - 35 USC § 112

The following is a quotation of the second of 35 U.S.C. 112:

16. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claim 26 provides for the use of polyhydroxyalkanoate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

18. Claim 29 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

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19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

20. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

21. Claim 1-17 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Sankaram et al U.S. Patent N0: 6,277,431

22. **Sankaram et al** discloses a polyhydroxyalkanoate that is biodegradable, col. 3, lines 4 -6 and is used for the treatment for cell and tissues col, 9, lines 17-20, (Claim1). Col. 7, lines 23-24 reads on range of molecular weight (claims 11-12). The reference further discloses that the composition includes proteins, peptides, steroids, and anesthetics col. 3, lines 32-41, hormones, antibodies, and anti-inflammatory agents, col.9 lines 1-11, (claim 15). Col. 3, lines 66-67 reads on drug delivery system, and further '431 reference discloses that the pharmaceutical composition (polyhydroxyalkanoate) can be administered by injection, (i.e. in a kit claim 31), col. 9, lines 36-37, (claim 31-32). Col. 10, lines 60-64 reads on aqueous solution (claim 6).

Col.12 lines 63-64 reads on the mean particle diameters of the polymer, (claims 7-9).

The reference further discloses in col. 11, lines 7-9 that the polymer is amorphous, (claim 17 and 30).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. *Claim 1-17 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggink et al WO 96/002,63.*

24. Eggink et al disclosed a polyhydroxyalkanoate, which is a biologically degradable aqueous dispersion and is used for treating (i.e. by injection via "kit") wounds (claims 1 and 5-6), see abstract and page 1 line 5-7. The reference '263 further discloses the temperature range (claims 2-4) on page 6, lines 38-39 and page 8, lines 2-7. Page 8, lines 38-39 and page 9, lines 1-3 reads on dyes, anti-fungal agents, , anti-microbial and other agents, (refers to anti-microbial, ant-inflammatory,) in claim 15)

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. *Claim 1-17 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchessault et al WO 91/13207.*

26. Marchessault et al discloses a biocompatible and biodegradable polyhydroxyalkanoate see abstract, and page 3, 3rd paragraph, for treatment (i.e. by

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injection via a kit) and control delivery of drugs. The '207 reference discloses, surface coating, (refers to surfactants) adjuvants, anti-bacterials (refers to anti-microbials) page 14, lines 8-13. See page 18 for chloroform vapors (anesthetics) and protein (claim 15). See page 7 last paragraph for diameter of the granules (refers to particles in claims 7-9). See page 7, lines 24-26, which reads on viscosity (claims 13-14)

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

27. *Claim 1-17 and 29-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin et al WO 99/325,36.*

28. Martin et al disclose, a biocompatible and resorbable polyhydroxyalkanoate composition used for wound healing, see pages 9-10, (by injection via a kit claim 31), (claim 1). Page 7 lines 5-8 reads on the molecular weight in claim, (claims 11 and 12). The reference further discloses on page 15, line 7-8 that polyhydroxyalkanoate is amorphous (claims 17 and 30). See page 18, lines 26-29 and page 19 lines 1-3, for "the composition comprising an agent" in claims 15-16.

Claim Rejections - 35 USC § 102

29. The following is a quotation of the appropriate paragraphs of 35 U.S.C

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

30. Claim 1-17 and 29-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Williams et al WO 98/518,12.

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31. Williams et al disclose polyhydroxyalkanoateis used for tissue regeneration (refers to repair of tissue in claim 1, see the entire document, specially the abstract. See page 19 lines 15-33 that reads on polyhydroxyalkanoate coupled to other agents i.e. proteins peptides, antibodies, enzymes receptors ligands adhesion peptides, polysaccharides, synthetic organic and inorganic drugs etc, (Claims 15 and 16). Page 26 lines 10-12 reads on treatment of bone disease (claim 29). Page 29 lines 30-31 and page 30 lines 1-5 read on methods of administering the composition, systemically or locally or even in vitro, by injection (refers to claims 31 and 32, to a kit delivering the composition to a patient).

32. No claims are allowed.

General information regarding further correspondence

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tahira Bhatti whose telephone number is (703) 605-1203. The examiner can normally be reached between Monday to Friday from 8:00 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsana Venkat (art unit 1627), can be reached at (703) 308 0570. Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-0196

Tahira Bhatti (art unit 1627)

April 19, 2002

BENNETT CELSA
PRIMARY EXAMINER

